II

110TH CONGRESS
1ST SESSION

S. 2192

To establish a user fee for follow-up reinspections under the Federal Food, Drug, and Cosmetic Act.

IN THE SENATE OF THE UNITED STATES

OCTOBER 18, 2007

Mr. FEINGOLD introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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A BILL

To establish a user fee for follow-up reinspections under the Federal Food, Drug, and Cosmetic Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. ESTABLISHMENT OF USER FEE FOR FOLLOW-UP REINSPECTIONS.

(a) IN GENERAL.—The Secretary shall assess and collect a user fee from each manufacturer of a food, drug, device, biological product, or animal drug for which a follow-up reinspection is required to ensure correction of a violation, found by the Secretary during initial inspection of the manufacturer, of a Good Manufacturing Practices

requirement under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.).

(b) PAYMENT OF FEE.—The user fee required by subsection (a) shall be due from a manufacturer upon the reinspection of the manufacturer as described in subsection (a).

(c) AMOUNT OF USER FEE.—The amount of the user fee required under subsection (a) shall be established by the Secretary.

(d) DEFINITIONS.—For purposes of this section—

(1) the terms ''animal drug'', ''device'', ''drug'', and ''food'' have the meanings given those terms in section 201 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321);

(2) the term ''biological product'' has the meaning given the term in section 351 of the Public Health Service Act (42 U.S.C. 262); and

(3) the term ''Secretary'' means the Secretary of Health and Human Services.

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